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LOUIS WOO
LAW OFFICE OF LOUIS WOO
717 NORTH FAYETTE STREET
ALEXANDRIA, VA 22314

EXAMINER	
WILLIAMS, CATHERINE SERKE	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/783,967
Filing Date: February 16, 2001
Appellant(s): ALESI, DANIEL E.

Louis Woo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 19, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is substantially correct.

Appellant cites to a restriction requirement dated July 23, 2002. The actual mailing date of the restriction requirement was July 2, 2002.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is substantially correct.

The first sentence of Appellant's summary refers to claim 1 which is not being appealed and not pending. Claim 1 was cancelled in the preliminary amendment cited in the status of claims. However, the description is accurate for independent claim 39 which is pending and appealed. It is believed that this is a typographical error and Appellant intended to refer to claim 39.

Additionally, claim 38 is referred to on line 12 of Appellant's summary in error as an independent claim. It is again believed that this is a typographical error and Appellant intended to refer to independent claim 48 which recites "a winged body".

Aside from these typographical errors, Appellant's summary is accurate.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 39-43,44-47 and 48-52 stand or fall together because Appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,746,726	***SWEENEY et al***	***5-1998***
6,436,086	***NEWBY et al***	***8-2002***
5,643,219	***BURNS***	***7-1997***

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al (USPN 5,746,726) in view of Newby et al (USPN 6,436,086) in further view of Burns (USPN 5,643,219).

Regarding independent claims 39 and 44, Sweeney discloses a device that includes a body (52) having a through passage (68) connecting its one end to its other end, a needle (14) extending from the one end and the other end attached to a syringe. See figures 3,4,8 and 10. A fluid communication pathway is established between the needle (14) and the syringe barrel interior through the body (52) and could be used to inject or withdrawal fluids. See figures 5-8. A housing (36) is hingedly (50) attached to and extends from the needle end of the body (52) and is pivotable (see figures 3 and 7-8) to a position in substantial alignment along the longitudinal axis of the body so as to envelop the needle (see figures 5-6 and 8).

Regarding dependent claims 40-43 and 45-47, locking means (generally 54) are integrated to the housing for fixedly retaining the needle within the housing once the needle is enveloped by the housing. See figure 5. The locking means includes a hook (56) that snaps over the body and retains the needle within the housing when the housing is pivoted substantially to the alignment position. See figure 6. The locking means comprise at least one pair of fingers/locking means on the body and the housing (56-housing and 58-body) that coact to prevent the needle from being removed from the housing once the housing is pivoted to envelope the needle. See figures 5 and 6.

Regarding independent claims 39 and 44, Sweeney meets the claim limitations as described above but fails to include the body being connected to flexible tubing instead of a syringe at the other end from the needle. However, Newby discloses a safety shield for a medical needle (fig 17) that includes a housing (140a) hingedly connected to a body (90a and 204) having wings (204) and a needle (206) at one end. Additionally, on the other end of the body from the needle is connected flexible tubing (208). The other embodiments show the pivotable housing attached to a syringe and a vacutainer port.

At the time of the invention, it would have been obvious to substitute the syringe of Sweeney for flexible tubing as taught by Newby. The devices are analogous in the art and with the instant invention; therefore, a combination is proper. Additionally, both devices are structural and functional equivalents and utilize a pivotably hinged housing in order to protect a medical technician from being exposed to a needle stick after use. The motivation for the substitution would have been in order to provide the device of Sweeney with an alternate means of blood collection thereby enabling more blood to be collected in a container at the end of the flexible tubing, i.e. a blood bag, than would be able to be collected by a standard syringe.

Regarding independent claims 39 and 44, Sweeney in view of Newby meets the claim limitations as described above but fails to include (i) a housing molded to and integrally extending from the one end of the body (claim 39) and (ii) the housing and body being formed from a mold (claim 44). However, Burns discloses a shielded needle assembly formed by injection molding. Figures 4 and 6-7 best represent the device of Burns. The device of Burns includes a body (48) having a through passage (see figure 2) connecting its one end to its other

end, a needle (12) extending from the one end of body (48) and the other end connected to a vacutainer holder (34). A housing (38) is hingedly (56) attached to and extends from the needle end of the body (48) and is pivotable (see figures 6-7) to a position in substantial alignment along the longitudinal axis of the body so as to envelop the needle. Burns discloses "It is preferred that shield 38 and mounting 48 with first portion 50 and hinge 56 be formed as a unitary article of manufacture. Hinge 56 preferably is formed as a "living hinge" when the shield and mounting are formed. Preferably shield 38 and mounting 48 are formed by injection molding a thermoplastic resin." See 5:34-39. Burns states that "the needle assembly of the present invention is simple to manufacture". See 3:6-7. The needle assembly includes the housing, hinge and body. See 4:11-27. Burns further shows fingers (58) that connect to the base once positioned around the needle to prevent the needle from being re-exposed after use.

At the time of the invention, it would have been obvious to incorporate the teaching of the injection molded construction of Burns into the invention of Sweeney in view of Newby and make the body (52) hinge (50) and housing (36) of Sweeney a unitary article of manufacture. All three inventions are analogous in the art and with the instant application; therefore, a combination is proper. All three references teach almost identical structures for the same function of preventing needle sticks after use. Additionally, forming multiple components from the same mold is well known in the needle shield art and Burns himself provides a motivating statement in that "The needle assembly of the present invention is simple to manufacture". See above. The motivation for making the combination would have been to enhance the manufacturing of the device since the advantages of molding are very well known in the art, one of them being simplicity as provided by Burns.

Claims 39-41, 44-46 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newby et al (USPN 6,436,086) in view of Burns (USPN 5,643,219).

Regarding independent claims 39, 44 and 48, Newby discloses a safety shield for a medical needle (fig 17) that has a housing (140a) hingedly connected to a body (both elements 90a and 204) having a needle (206). It is considered inherent that the body includes a through passage connecting its one end to its other end in light of the fact that the needle (206) which is embedded in the body (204) extends through the body (90a) from the one end to the other end which can only occur if body (90a) has an internal bore. Likewise, body (204) must have a through passage to make fluid communication between the needle (206) and tubing (208). Additionally, the other embodiments of body (90) show such a through passage (see figure 2 and 4 which shows a through passage in body 90). The proximal portion of the body (204) has wings (see figure 17). Additionally, on the opposite side of the body (90a and 204) from the needle is connected flexible tubing (208).

Regarding dependent claims 40-41, 45-46 and 49-52, a locking means is best seen in figure 16. Fingers (194) hold the housing in the retaining needle position by their connection with coacting fingers (118).

Regarding independent claims 39,44 and 48, Newby meets the claim limitations as described above but fails to include (i) a housing molded to and integrally extending from the one end of the body (claims 39 and 48) and (ii) the housing and body being formed from a mold (claim 44). However, Burns discloses a shielded needle assembly formed by injection molding.

Figure 4 and 6-7 best represent the device of Burns. The device of Burns includes a body (48) having a through passage (see figure 2) connecting its one end to its other end, a needle (12) extending from the one end of body (48) and the other end connected to a vacutainer holder (34). A housing (38) is hingedly (56) attached and extends from the needle end of the body (48) and is pivotable (see figures 6-7) to a position in substantial alignment along the longitudinal axis of the body so as to envelop the needle. Burns discloses "It is preferred that shield 38 and mounting 48 with first portion 50 and hinge 56 be formed as a unitary article of manufacture. Hinge 56 preferably is formed as a "living hinge" when the shield and mounting are formed. Preferably shield 38 and mounting 48 are formed by injection molding a thermoplastic resin." See 5:34-39. Burns states that "the needle assembly of the present invention is simple to manufacture". See 3:6-7. The needle assembly includes the housing, hinge and body. See 4:11-27. Burns further shows fingers (58) that connect to the base once positioned around the needle to prevent the needle from being re-exposed after use.

At the time of the invention, it would have been obvious to incorporate the teaching of the injection molded construction of Burns into the invention of Newby and make the body (90a), hinge and housing (140a) of Newby a unitary article of manufacture. Both inventions are analogous in the art and with the instant application; therefore, a combination is proper. Both references teach almost identical structures for the same function of preventing needle sticks after use. Additionally, forming multiple components from the same mold is well known in the needle shield art and Burns himself provides a motivating statement in that "The needle assembly of the present invention is simple to manufacture". See above. The motivation for making the combination would have been to enhance the manufacturing of the device since the

advantages of molding are very well known in the art, one of them being simplicity as provided by Burns.

(11) Response to Argument

Appellant's first argument is "Sweeney does not disclose any body that has a through passage to which one end has a needle and another end has a flexible tube" and "Newby likewise fails to disclose a body that has a through passage." See Argument page 6, last three lines and page 7, line 10. However, the above rejection and the previous rejections entered into the application record consistently indicate that element # 52 of Sweeney is relied on as the body. A through passage is disclosed as # 68 and is clearly shown in figure 10 where the syringe luer (24) and needle (14) reside within the passage (68) of the body (52). As shown in figure 4, from one end of the body (52) extends a needle (14) and the other end connects to a luer (24) for attachment to a syringe.

The above rejection states that Sweeney alone fails to teach the flexible tube. Hence, the 35 U.S.C. 103(a) rejection using Sweeney et al in view of Newby et al. Newby is relied on to teach substituting the syringe of Sweeney with a flexible tube. The combination of the body (52), passage (68) and needle (14) of Sweeney with the flexible tubing of Newby meets the claim limitations of "a body having a through passage connecting its one end to its other end, a needle extending from said one end and a flexible tubing connected to said other end."

Appellant's second argument is neither Burns nor "any of the references relied upon by the examiner suggests the unitary molded device of the instant invention that includes both a main body having attached thereto a needle and a flexible tube, and an integrally connected housing." See Argument page 7, lines 20-23. Burns clearly discloses injection molding the

body, hinge and housing. "It is preferred that shield 38 and mounting 48 with first portion 50 and hinge 56 be formed as a unitary article of manufacture. Hinge 56 preferably is formed as a "living hinge" when the shield and mounting are formed. Preferably shield 38 and mounting 48 are formed by injection molding a thermoplastic resin." See Burns 5:34-39.

In summation, Appellant argues "there is nothing in any of the cited references that suggests a single unitary device." See Arguments page 8, line 1. However, none of the claims recite "a single unitary device". In general, appellant's arguments are directed to asserting that the combination of references do not show "the complete device from a single mold" rather than what appellant chose to claim. See Arguments page 6, line 19. Appellant has not claimed a complete device from a single mold. The only limitations in the claims that are molded or unitary are the body, hinge and housing. The claims recite that the needle extends from one end of the body and the flexible tubing is connected to the other end. The terms extends or extending and connected to do not impart molded, integral or unitary. In total, only three elements are claimed as molded or unitary or integral, i.e. the body, hinge and housing. However, Appellant asserts that since the prior art alone and both rejections under 35 U.S.C. 103(a) do not show an entire device being molded from one single mold these references and the rejections using the combination of references does not show the device as claimed. This argument is flawed since appellant is not arguing the invention as claimed but rather the invention as perceived through the drawings and specification. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellant then further continues to argue the definition that should be used when interpreting integral. Arguments page 8, line 6 to page 9, line 24. Even if one concedes and uses Appellant's provided definition of integrated, it is believed that Burns clearly teaches Appellant's definition of integral or integrated. Burns discloses a housing molded to and integrally extending from one end of the body and a housing formed from the same mold as the body and integrally attached to the body. Burns teaches using an injection molding process to form the housing, body and hinge as "as a unitary article of manufacture." See Burns 5:35-36. Clearly, Burns teaches the structure as claimed even using Appellant's definition of integral/integrated.

Additionally, the court has held that the use of a one-piece construction is an obvious modification unless the invention in question perceived a need/problem in the art and by making integral solved the known problem. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). Schenck v. Nortron Corp., 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). In Larson, the one-piece construction was found obvious as a matter of obvious design choice. Conversely, in Schenck a perceived problem was solved by the integral construction and the integral construction was therefore patentable.

Appellant cites the reason for making the one-piece construction as "for ease of manufacture, it may be advantageous to mold the safety device and the IV infusion assembly as a single unit". See Specification Page 2, lines 3-4. This motivation does not meet the above test. Appellant's device is molded or unitary as a matter of design choice. Appellant's reason for making the body, hinge and housing as molded, unitary and integral is common in the art. Burns uses the same rational for injection molding his body, hinge and housing, i.e. "the needle

assembly of the present invention is simple to manufacture". See Burns 3:6-7. Appellant does not site a perceived problem in the art as the reason his body, hinge and housing are molded or integral. Clearly, Appellant's choice to mold or make integral the body, hinge and housing is obvious and not patentable for the same reason the invention of Larson was not patentable.

Finally, appellant asserts "that none of the prior art discloses or suggests a pair of fingers coacting to prevent the needle from being removed from the housing once the housing is pivoted to envelope the needle". See Arguments page 9, last paragraph. The above rejection and the previous rejections indicate that element #s 56 and 58 of Sweeney and element #s 194 and 118 of Newby are the claimed locking means/fingers. Clearly, these are structural equivalents of the claimed locking means/fingers.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Catherine S. Williams CSW.
September 27, 2004

Conferees
Nicholas D. Lucchesi
Angela D. Sykes

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

LOUIS WOO
LAW OFFICE OF LOUIS WOO
1901 NORTH FORT MYER DRIVE
SUITE 501
ARLINGTON, VA 22209